REMARKS

I. Status of the Claims

Claims 12, 15-17, 20-24, 63 and 64 were pending in the July 22, 2010 Office Action. With this Reply, claims 12, 16, 20, 22, 23, and 64 are amended and claims 15 and 63 are canceled. The claim amendments and cancelations are made without prejudice or disclaimer, and introduce no new matter. Claims 12, 16, 17, 20-24 and 64 are presented for reconsideration.

II. Rejection under 35 U.S.C. 112, First Paragraph - Enablement

Claims 12, 15-17, 20, 22-24 and 63-64 are rejected under 35 U.S.C. 112, first paragraph, enablement requirement. Applicants request reconsideration and withdrawal of this rejection in light of the claim amendments and the following comments.

The instant specification describes a study comparing certain immune system parameters in patients with and without Gaucher's disease and with and without HCV. For the instant claims, the most important comparison is between HCV patients with and without Gaucher's disease. As shown in the figures, Gaucher's patients with HCV had increased HCV-specific T cells (FIG. 1), increased HCV-specific IFNγ-producing cells (FIG. 2), increased HCV-specific IL10-producing cells (FIG. 3), increased IFNγ serum levels (FIG. 4), increased IL-4 serum levels (FIG. 5), and increased peripheral NKT lymphocytes (FIG. 6), when compared to HCV patients without Gaucher's disease. All of the increased parameters found in Gaucher's patients with HCV vs. HCV patients alone would be understood by the skilled artisan to be beneficial in fighting HCV. For example, the increase in HCV-specific T cells indicates that a Gaucher's + HCV patient has increased immunity against HCV over an HCV patient without Gaucher's. Also, IFNγ is a known treatment for HCV and the increased level is Gaucher's + HCV patients would thus be considered to be beneficial. Additionally, the increased anti-inflammatory cytokines IL10 and IL4 in Gaucher's + HCV patients vs. HCV alone would be

considered beneficial in that the reduced inflammation caused by those cytokines would lead to less HCV-induced liver damage. See also the specification at page 3, describing the unexpected lack of cirrhosis in Gaucher's patients. Thus, Gaucher's patients with HCV have a more effective immune reaction to HCV than patients with HCV alone.

As discussed in the specification at page 1, Gaucher's disease is caused by "...a buildup of glucosylcerebroside due to a decreased capacity for breakdown of this product." Thus, the skilled artisan would understand that having Gaucher's disease is therapeutically equivalent to being treated with glucosylcerebroside (a monosaccharide ceramide). Given the instant specification, that skilled artisan would therefore understand that treatment of an HCV patent with a mammalian monosaccharide ceramide (such as glucosylcerebroside), as claimed, would lead to the same beneficial immune parameters against the HCV infection as was seen in the Gaucher's + HCV patients. Thus, although the Office Action asserts, on p. 15, that "[t]he specification does not contain any working examples demonstrating the effective use of glycolipids to treat HCV infection," the skilled artisan would understand that a Gaucher's patient with HCV is, in effect, equivalent to treating an HCV patient with glucosylcerebroside. The specification thus does provide an example of the equivalent of treatment of an HCV patient with glucosylcerebroside. Indeed, the Office Action provides no reason for believing that a Gaucher's patient with HCV is not the equivalent to treating an HCV patient with glucosylcerebroside.

Additionally, Applicants disagree with the statement in the Office Action at page 12 that "[t]here is no information provided in the specification detailing the type of immune parameter that should be modulated to treat HCV or any disease. There is no information provided in the specification regarding the specific immune parameter that a particular metabolite/glycolipid modulates and how the modulation results in the treatment of HCV." In this regard, a review of the specification clearly indicates that immune parameters modulated by the excess of glucosylcerebroside experienced in HCV patients with Gaucher's disease include increased HCV-specific T cells, increased

HCV-specific IFNγ-producing cells, increased HCV-specific IL10-producing cells, increased IFNγ serum levels, increased IL-4 serum levels, and increased peripheral NKT lymphocytes, all of which would be understood by the skilled artisan to be beneficial in mounting an immune response to HCV, as discussed above.

Applicants also note that monosaccharide ceramides that are mammalian intermediate metabolites, as recited in the claims, are all very similar compounds that are known to have similar biological effects. Thus, treatment of an HCV patent with any mammalian monosaccharide ceramide would likely lead to the beneficial immune profile exhibited by Gaucher's patients with HCV.

Applicants further disagree with the assertion, at page 17-18 of the Office Action, that "[t]he skilled artisan cannot rely on the disclosure set forth in the specification to reasonably practice the invention without the burden of undue experimentation. In order for the skilled artisan to successfully practice the claimed invention, the skilled artisan would have to blindly and unduly experiment with glycolipids, each immune component, and determine the relationship among the glycolipids, each immune components and HCV infection." In response, Applicants first note that the claims as amended are directed to treatment with a mammalian monosaccharide ceramide. As discussed above, mammalian monosaccharide ceramides are a narrow class of glycolipids that are known to have similar biological activities. Applicants thus assert that the skilled artisan would understand that treating an HCV patient with any mammalian monosaccharide ceramide would be likely to lead to a change in the immune profile of the subject, where the immune profile would be expected to exhibit increased HCV-specific T cells, increased HCV-specific IFNγ-producing cells, increased HCV-specific IL10-producing cells, increased IFNγ serum levels, increased IL-4 serum levels, and increased peripheral NKT lymphocytes. As such, the only parameter of the claimed invention that is not specifically provided is the dose of mammalian monosaccharide ceramide that would lead to the favorable immune profile described above. In that regard, the skilled artisan would understand that a dose of mammalian monosaccharide ceramide that would lead to levels equivalent to that experienced by a Gaucher's patient

would certainly be an effective treatment. Further, it would be understood that determining how much the dose could be decreased to still lead to the favorable immune profile shown by the Gaucher's patients would not be considered to be undue experimentation.

Based on the above discussion, it is clear that the specification, at the time of filing, would have taught the skilled artisan how to practice the full scope of the claimed invention without undue experimentation, since treatment of an HCV patient with a mammalian monosaccharide ceramide, as claimed, would be understood to lead to the same anti-HCV immune profile as exhibited by a Gaucher's patient with HCV. Withdrawal of the enablement rejection under 35 U.S.C. 112, first paragraph is thus respectfully requested.

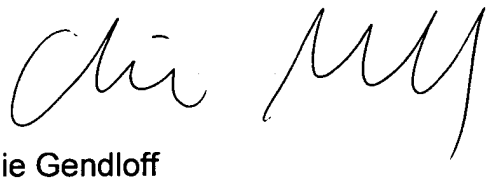
III. Conclusion

In view of the foregoing remarks, Applicants respectfully request withdrawal of the rejections of record and examination of the claims with respect to cancer, other viral infections, and autoimmune diseases (nonselected subject matter encompassed by claim 12).

The United States Patent and Trademark Office is hereby authorized to charge the extension of time and the RCE fees, as well as any other fees required to maintain pendency of this application, to Deposit Account No. 05-1135.

If a telephone conversation would further the prosecution of the present application, Applicants' undersigned attorney requests that he be contacted at the number provided below.

Respectfully submitted,



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